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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,449	03/13/2001	Fu-Tong Liu	051501/027 8726	9750

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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/805,449	LIU ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/24/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *14-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/16/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Claims 1-35 are pending in this application and were subject to restriction in Paper No. 6 dated 8/19/02. In Paper No. 7, Applicants elected Group I, claims 1-7. Since no traversal was provided in the response, this election will be treated as an election without traverse. Therefore, this restriction is deemed proper and is made FINAL. However, upon further consideration, the Examiner has combined Group II, claims 8-13 as part of the elected invention since examination of claims 1-13 would not be an undue search burden. Therefore claims 1-13 will be examined.

2. Specification

A. The specification is objected to since there is no description of Figure 12 in the Brief Description of the Drawings.

B. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title refers to the galectin proteins themselves whereas the claims are drawn to method of using these proteins. The following titles, for example, are suggested: "Methods of modulating cell migration using galectin-3," or "Methods of modulating galectin-3 receptor-expressing cells."

3. Claim Rejections - 35 USC § 112, first paragraph – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These are genus claims. The galectin-3 proteins used in the claimed methods are proteins with one or more amino acid substitutions, deletions, insertions and/or additions to the galectin-3 disclosed in the instant specification. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants,

and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class (e.g. galectin-1, 2 and 4-8) are missing from the disclosure. No common structural attributes identify the members of the genus. The specification refers to, and uses, only one galectin-3. No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical amino acid residues which would structurally characterize the genus of galectin-3 proteins claimed, because it is unknown and not described what structurally constitutes any different galectin-3 proteins, or galectin-3 proteins from any different species

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "galectin-3" alone is insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus; thereby not meeting the written description requirement under 35 USC 112, first paragraph. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

4. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 5 recites that the galectin-3 comprises an N-terminal or C-terminal subsequence of galectin-3. However, it appears from the specification that galectin-3 is a full-length protein which comprises both an N- and C-terminus. The implication in claim 5 is that a galectin-3 protein is considered a galectin-3 protein even if it only comprises an N- or C-terminus, as opposed to needing to comprise the full-length protein. Therefore, one cannot differentiate between a galectin-3 which comprises a C-terminus, one which comprises an N-terminus, and the full-length galectin-3. It is suggested that claim 5 be amended to recite, for example, "wherein said method uses a fragment of galectin-3..." or "wherein said method uses an N-terminal or C-terminal subsequence of galectin-3," thereby removing the

implication that galectin-3 is an N- or C-terminal subsequence of itself. The question raised as to the structure of galectin-3 renders all of the claims indefinite.

B. Claims 1-13 are also confusing since the metes and bounds of "galectin-3" are not known. It is not clear from the claims or disclosure what structurally constitutes a galectin-3 protein and how one is able to differentiate a galectin-3 from, for example, galectins 1, 2, or 4-8. Simply, it is not known what makes galectin-3, galectin-3.

C. Claims 3, 4 and 8-13 are confusing since it is not understood how galectin-3 binding polypeptides, or galectin-3 receptor binding polypeptides, both which could be, for example, antibodies, can stimulate migration, especially given the data in the specification (e.g. Fig. 2) showing that anti-galectin-3 antibodies inhibit migration. A similar situation holds true for claim 4 since it is not clear how galectin-3 can inhibit migration (see e.g. Fig 1).

5. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al. (Glycobiology 4(1):5-12, 1994). The claims recite a method for modulating migration of a cell that expresses a galectin-3 receptor by contacting the cell with galectin-3, galectin-3 binding polypeptide, or galectin-3 receptor binding polypeptide. The claims also recite the use of this method for directing these cells to a tumor or infection site.

Hughes et al. teach that galectin-3 (i.e. Mac-2) is found in macrophages and that "extracellular matrix remodeling would be necessary for extravasation and hence the lectin ligation of surface glycoproteins in early recruitment of inflammatory macrophages, such as those present at inflammatory sites...may be significant" (page 10, left column, first full paragraph). Therefore, Hughes et al. teach that lectins (i.e. galectin ligands) are involved with macrophage migration (i.e. recruitment). Inherent in this teaching is the use of a "migration-modulating amount: of galectin. Since Mac-2 is another term for "galectin-3" then the lectins taught by Hughes et al. in this paragraph would inherently be galectin-3 ligands. Though Hughes et al. does not teach the use of galectin-3 to modulate the migration of

macophages to tumor sites, or infection, one of ordinary skill in the art would immediately envision that galectin-3 could be used to recruit (i.e. migrate) cells, such as macrophages, to sites of infection, or which require an inflammatory response, such as tumors.

6. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. in view of Hawkins et al. (US Patent No. 5,869,289). The teachings of Hughes et al. are taught in the above rejection under 35 USC 102. Hughes et al. do not specifically state that galectin-3 is involved in cell migration, nor do they specifically teach methods for modulating immune cells at tumor or infection sites, such as an in vivo treatment. Hughes et al. also do not teach the use of anti-galectin antibodies. However, Hawkins et al. do teach that galectins, including galectin-3, which is expressed on macrophages, have been implicated in cell migration, as well as neoplastic transformation, and immune responses (e.g. infection) and that galectin-3 plays a role in metastasis (i.e. cell migration; column 2, line 65 – column 3, line 50). Hawkins et al. also teaches pharmaceutical compositions for the use of galectin-8 and galectin-8 antibodies (column 27, lines 51-64) as well as the use of these anti-galectin-8 antibodies column 36, lines 55-59) and that galectin-8 in pharmaceutical compositions, can increase immune responses. Since galectin-3 as well as other galectins, including galectin-8, which are all part of the same family (column 1, lines 16-28) are involved with metastasis (column 4, lines 5-9; column 36, lines 43-62), cell growth and development, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have used galectin-3, or its antibodies as taught by both Hughes et al. and Hawkins et al. in the method Hawkins et al. used for galectin-8 in order to modulate cell migration.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 18, 2002